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In re Application of

Platz

Application Number

08/246,034

Filed

01-06-04

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703-979-1111

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US006673335B1

(12) **United States Patent**
Platz et al.(10) **Patent No.:** **US 6,673,335 B1**
(45) **Date of Patent:** **Jan. 6, 2004**(54) **COMPOSITIONS AND METHODS FOR THE
PULMONARY DELIVERY OF
AEROSOLIZED MEDICAMENTS**(75) **Inventors:** **Robert M. Platz**, Half Moon Bay, CA
(US); **John S. Patton**, San Carlos, CA
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CA (US)(73) **Assignee:** **Nektar Therapeutics**, San Carlos, CA
(US)(*) **Notice:** Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.(21) **Appl. No.:** **09/616,236**(22) **Filed:** **Jul. 14, 2000****Related U.S. Application Data**(63) Continuation-in-part of application No. 08/737,724, filed as
application No. PCT/US95/06008 on May 15, 1995, now
Pat. No. 6,231,851, and a continuation of application No.
08/423,515, filed on Apr. 14, 1995, now Pat. No. 6,582,728,
and a continuation-in-part of application No. 08/417,507,
filed on Apr. 4, 1995, now abandoned, which is a continu-
ation of application No. 08/044,358, filed on Apr. 7, 1993,
now abandoned, application No. 09/616,236, which is a
continuation-in-part of application No. 08/383,475, filed on
Feb. 1, 1995, now abandoned, and a continuation-in-part of
application No. 08/313,707, filed on Sep. 27, 1994, now
abandoned, and a continuation-in-part of application No.
08/309,691, filed on Sep. 21, 1994, now Pat. No. 5,785,049,
and a continuation-in-part of application No. 08/246,034,
filed on May 18, 1994, now abandoned, and a continuation-
in-part of application No. 07/910,048, filed on Jul. 8, 1992,
now Pat. No. 5,458,135.(51) **Int. Cl.⁷** **A61K 9/12; A61K 9/14**(52) **U.S. Cl.** **424/45; 424/46; 424/94.1;**
424/489; 514/2; 514/15(58) **Field of Search** **424/45, 46, 94.1,**
424/489; 514/2, 15(56) **References Cited****U.S. PATENT DOCUMENTS**4,659,696 A * 4/1987 Hirai et al. 514/15
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Freeze-Dried Formulations of Human Growth Hormone,"
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Primary Examiner—Michael G. Hartley**Assistant Examiner**—M. Haghighatian(74) **Attorney, Agent, or Firm**—Susan T. Evans; Mark A.
Wilson; Felissa H. Cagan(57) **ABSTRACT**According to the subject invention, dispersible dry powder
pharmaceutical-based compositions are provided, including
methods for their manufacture and dry powder dispersion
devices. A dispersible dry powder pharmaceutical-based
composition is one having a moisture content of less than
about 10% by weight (%w) water, usually below about 5%w
and preferably less than about 3%w; a particle size of about
1.0-5.0 μ m mass median diameter (MMD), usually 1.0-4.0
 μ m MMD, and preferably 1.0-3.0 μ m MMD; a delivered
dose of about >30%, usually >40%, preferably >50%, and
most preferred >60%; and an aerosol particle size distribu-
tion of about 1.0-5.0 μ m mass median aerodynamic diam-
eter (MMAD), usually 1.5-4.5 μ m MMAD, and preferably
1.5-4.0 μ m MMAD. Such compositions are of pharmaceu-
tical grade purity.**26 Claims, No Drawings**